Image-Guided Interventions

Requirements and Planning

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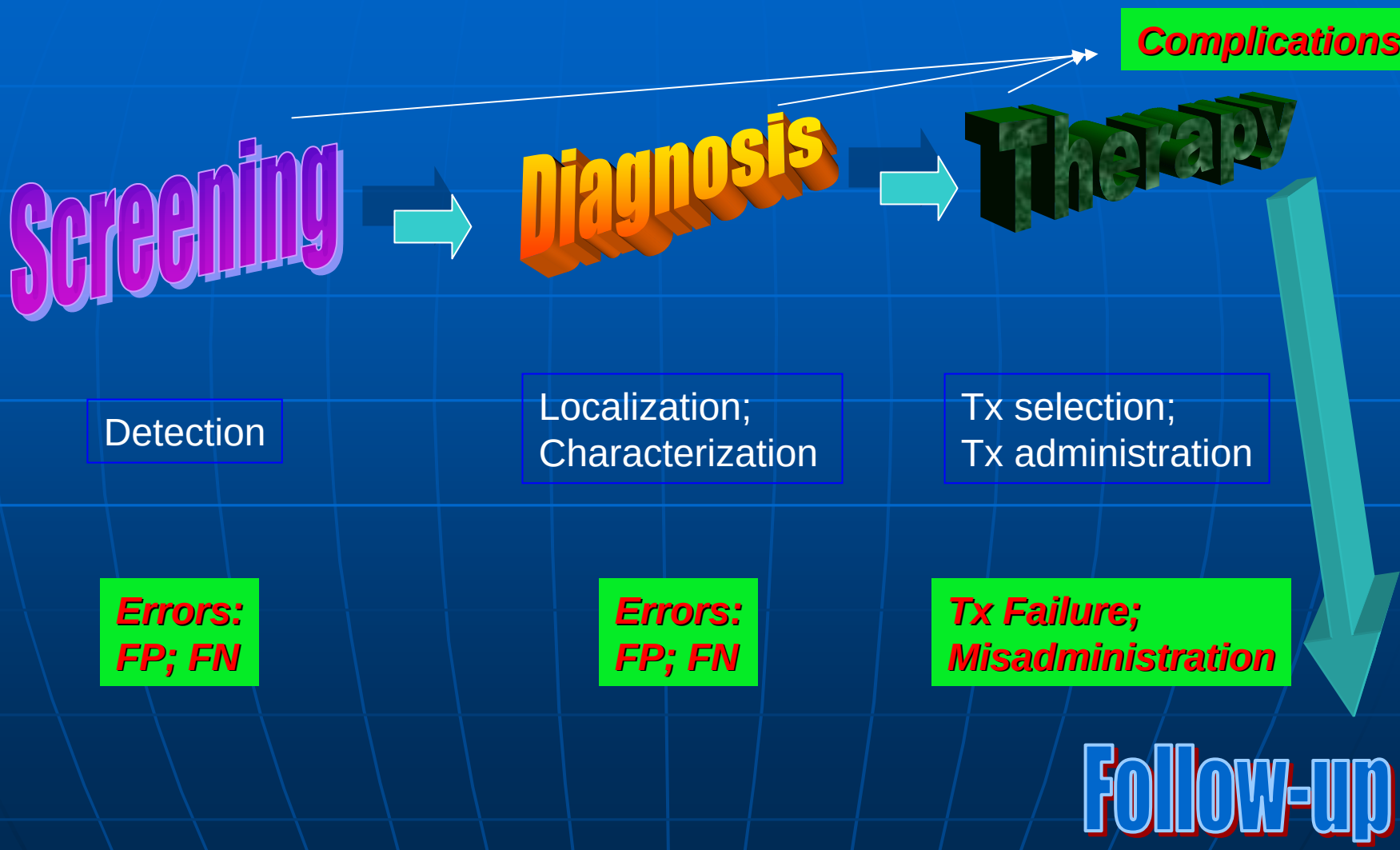
Outline

- Planning for IGI
- Example: Breast Biopsy
- New Requirements
  - Diagnosis after screening
  - Incidentalomas
- Clinical Trials

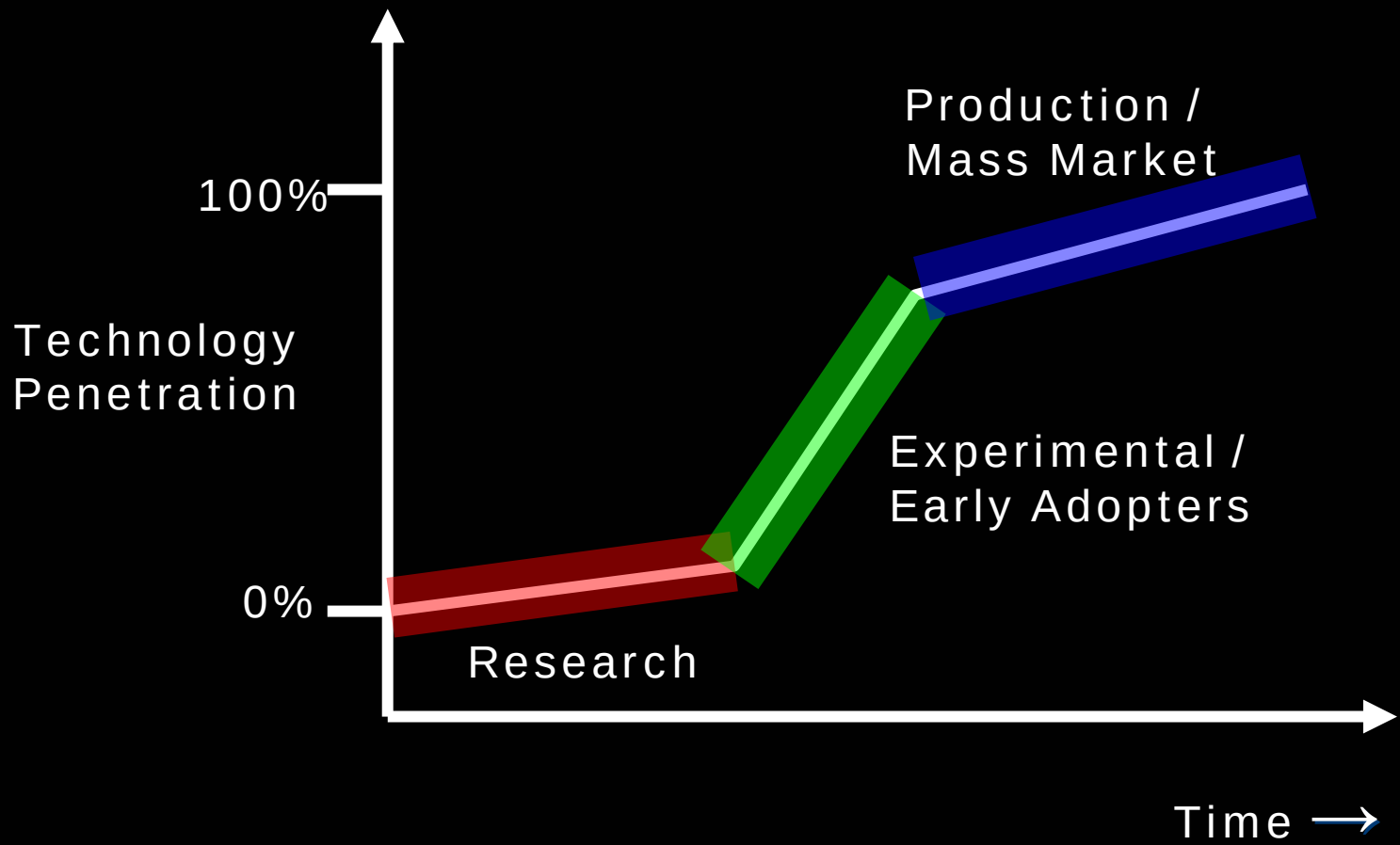
Definition of IGI

- Images required for procedure
  - May be pre-op or intra-op or both
- Target is present
- Images are used for guidance, navigation; orientation
- Operator is involved

Paradigm


Complications…
Screening
Diagnosis
Therapy
Detection
Localization;
Characterization
Tx selection;
Tx administration
Errors:
FP; FN
Errors:
FP; FN
Tx Failure;
Misadministration
Follow-up

Technology Adoption S-Curve



Minimally Invasive Surgery

- The global market for MIS is currently over $3 billion, though less than 15% of all surgeries are performed using an MIS approach.

- Advanced procedures, such as Cardiac Surgery, Colon Surgery, Hysterectomy, and Discectomy/Spine Fusion, account annually for over 15 million procedures worldwide, yet have no widely accepted MIS approach.

Planning Methods

- Breakthrough (Hoshin)
- Quality (House of Quality, Quality Function Deployment)
- Six Sigma
- Technology Roadmapping
- Kano (Unspoken requirements)
- Usability (Poke-Yoke)
- and many others...

Image Analysis and Visualization

Report of Working Group 4
Medical Imaging Technology Roadmap
June 30, 2000

Goal: To provide a market-driven forecast of technologies needed to improve patient care and enhance the global competitiveness of the Canadian medical imaging sector.

http://strategis.ic.gc.ca/medimage

Section 5

IMAGE ANALYSIS AND VISUALIZATION FOR IMAGE-GUIDED THERAPY

- Goals
- Description
- Alternatives
- Maturity And Risk
- Availability
- Breadth of Application
- References
- Contacts

Executive Summary

- Image-guided surgery and therapy offers a less invasive, less costly approach to patient care for a number of procedures.
- However, the requirements for a successful system are demanding.

- Subheadings:
  - accurate systems for instruments tracking in the body;
  - flat-panel stereoscopic display systems;
  - heads-up display systems;
  - automatic patient-image registration;
  - force feedback technologies for visualization;
  - surface matching; and
  - bone-mounted markers.
  - user interface tools
    - Virtual Reality displays,
    - high speed interaction,
    - haptic feedback,
    - robotics,
    - stereoscopic and head-mounted displays.

Scibermed Virtual Institute

http://www.scibermed.com/

Biomedical Research Foundation of Northwest Louisiana

SVI's Objectives:

Minimally Invasive Therapy, Imaging, and Energy Delivery Technology and Policy Objectives and Roadmaps

SVI's Objectives (technology)

1. To develop image-based methods of **tissue identification and characterization** and multimodal image display technologies…

2. To enhance and expand innovative methods of **tissue reconstruction and ablation**…

3. To develop methods to accomplish therapy using the **least invasive** access route feasible….

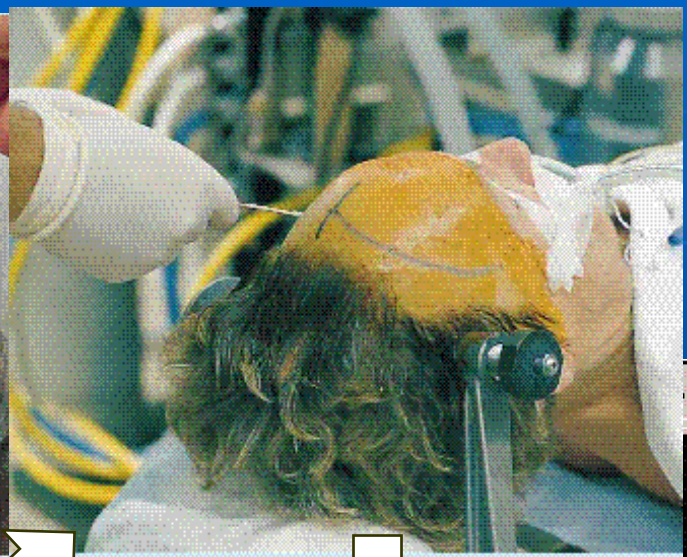
4. To develop a system for … **rapidly disseminating** new, effective minimally invasive therapies …

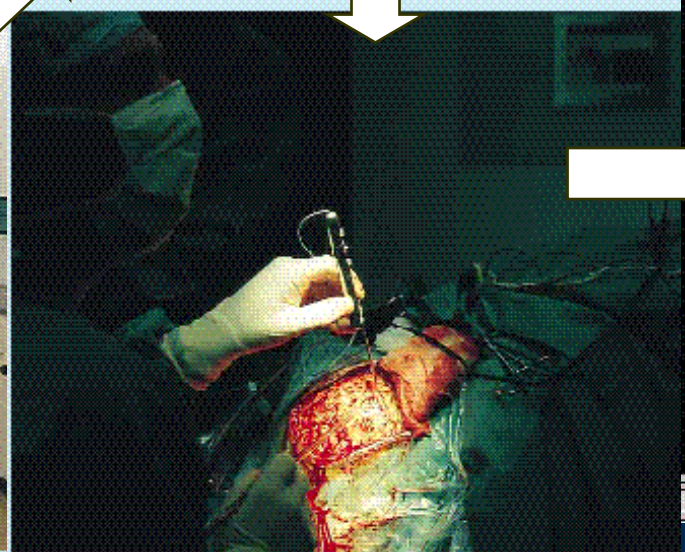
IGI – Pro and Con

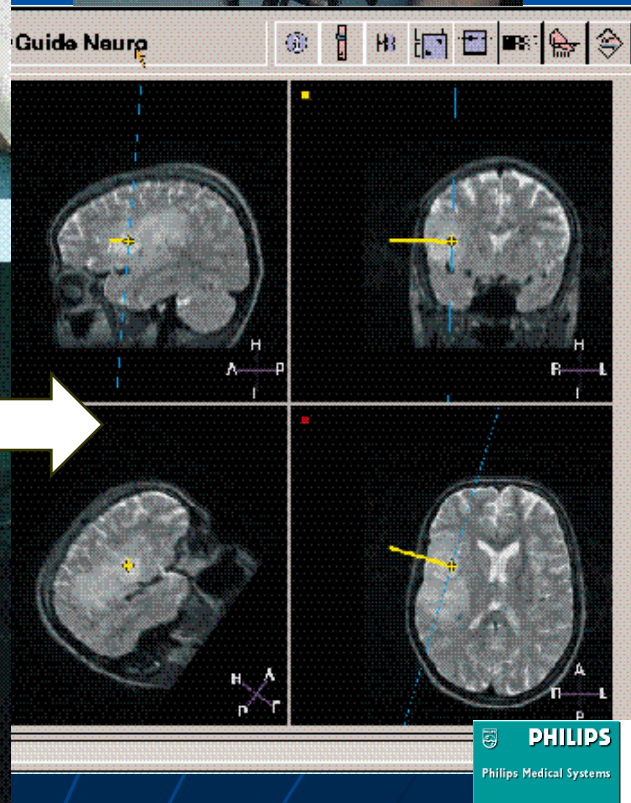
- **Positive**
  - Less invasive
  - May be very fast
  - Correlation with function possible
  - Better precision
  - Fewer complications (NTC)
  - Assures “completeness”
  - High tech approach
    - (better marketability)
- **Negative**
  - Imaging may be superfluous
    - (e.g., palpable lesion)
  - Images may be seductive; lead to overdiagnosis
  - Images may be incorrect
    - (need updates)
  - Higher cost and complexity
    - Reimbursement uncertainties
  - Operator-dependent
    - (variability)
  - Requires special equipment and training

Imaging in Therapy

Frameless Stereotaxy







object horizontal rotation

object elevation

object roll

reset object orientation

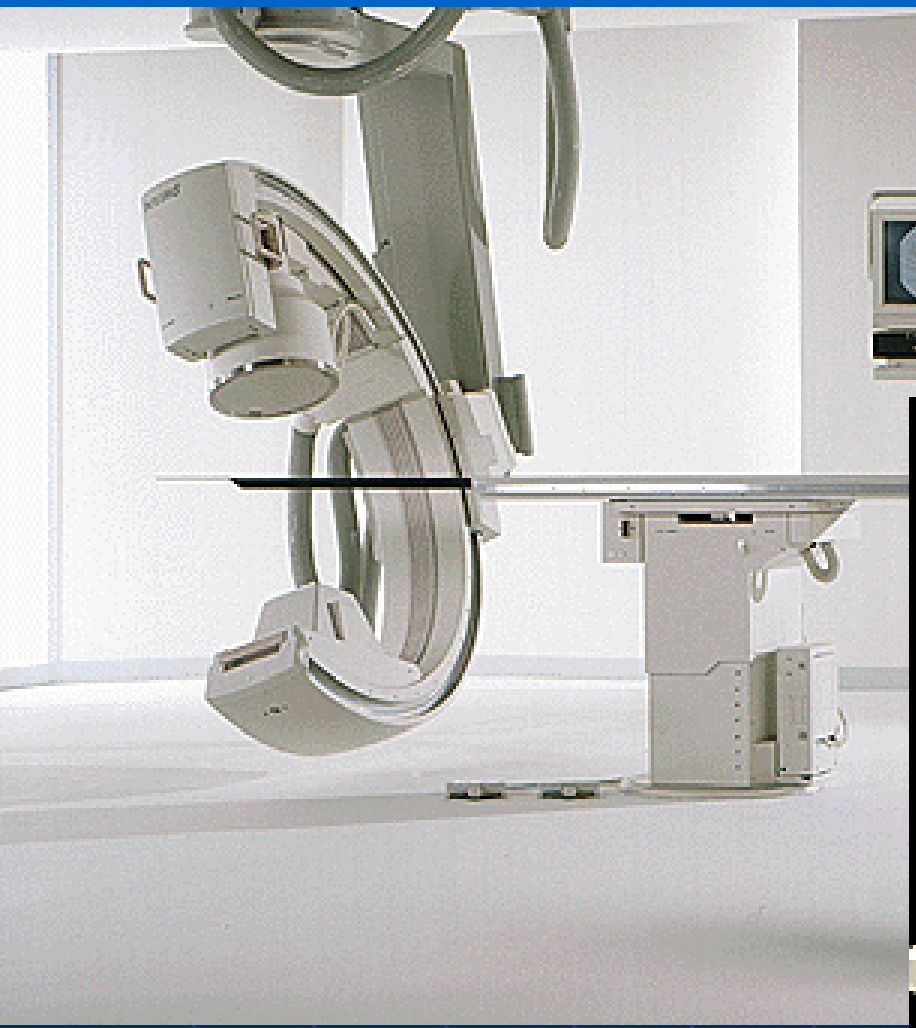
light source horizontal rotation

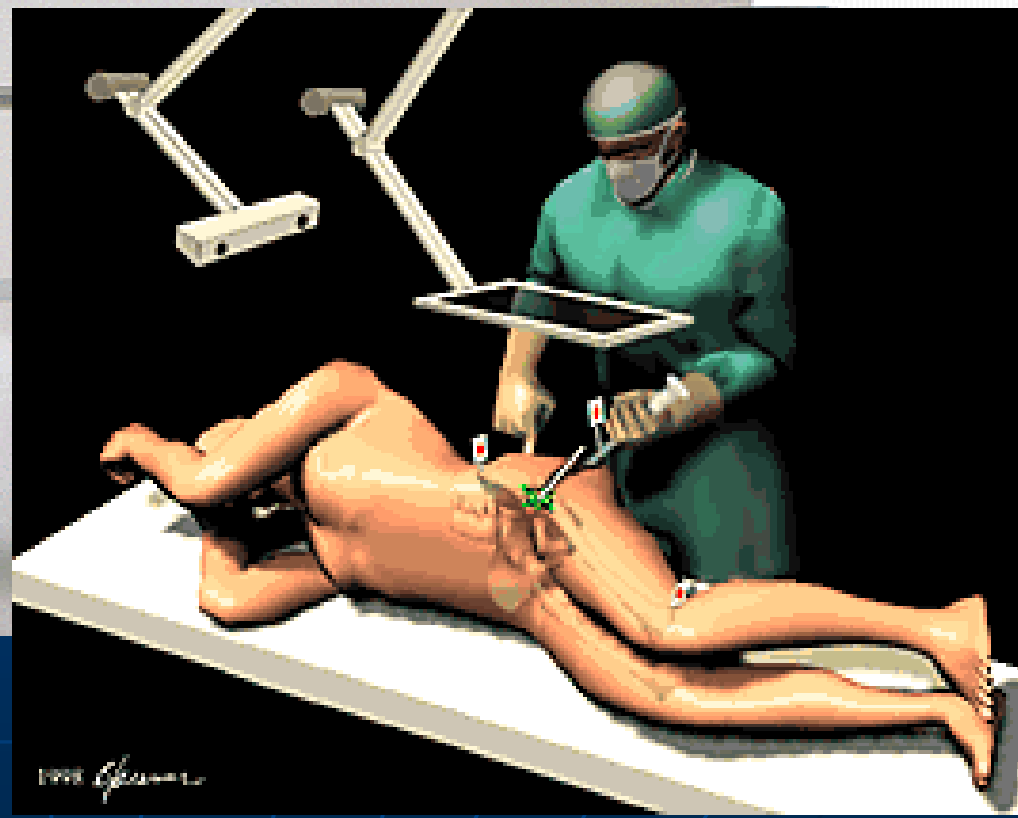
light source elevation

reset light source

percents

WW/WL





Computer Integrated Surgery

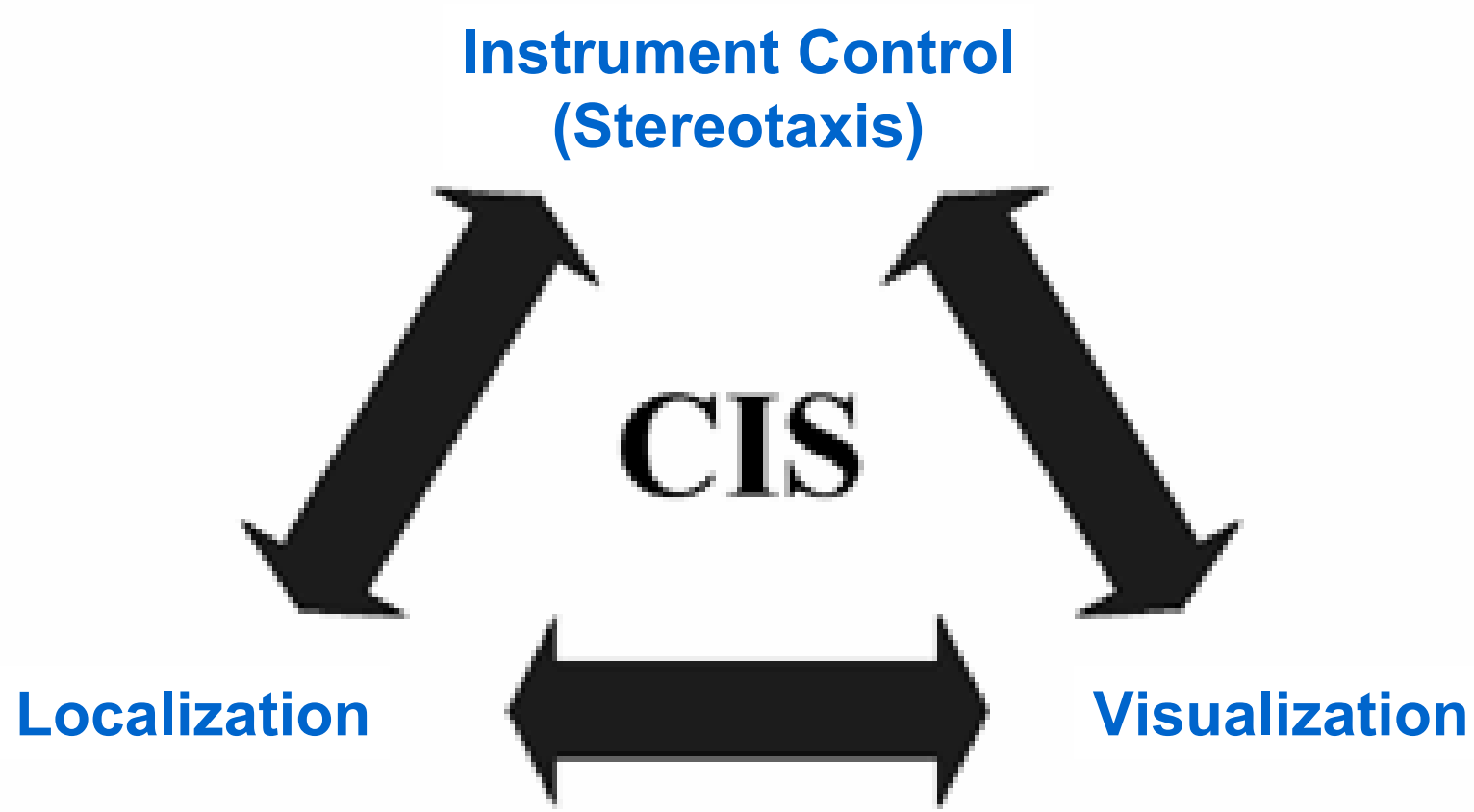
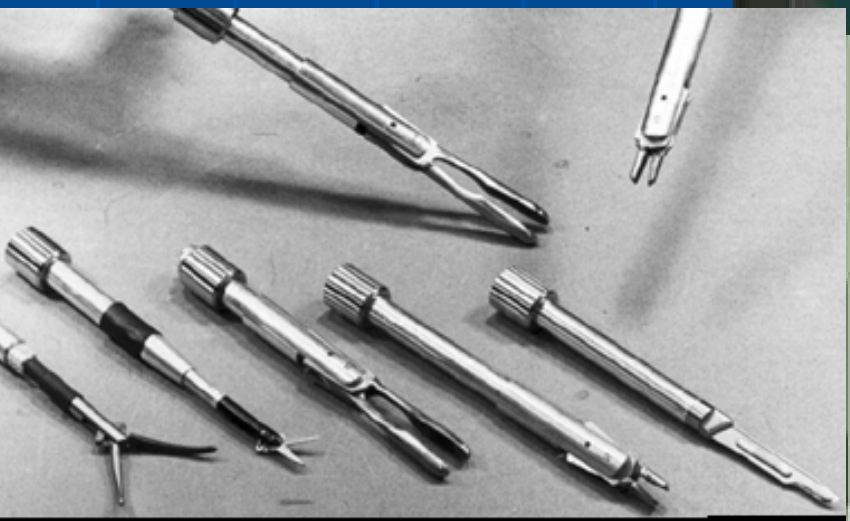
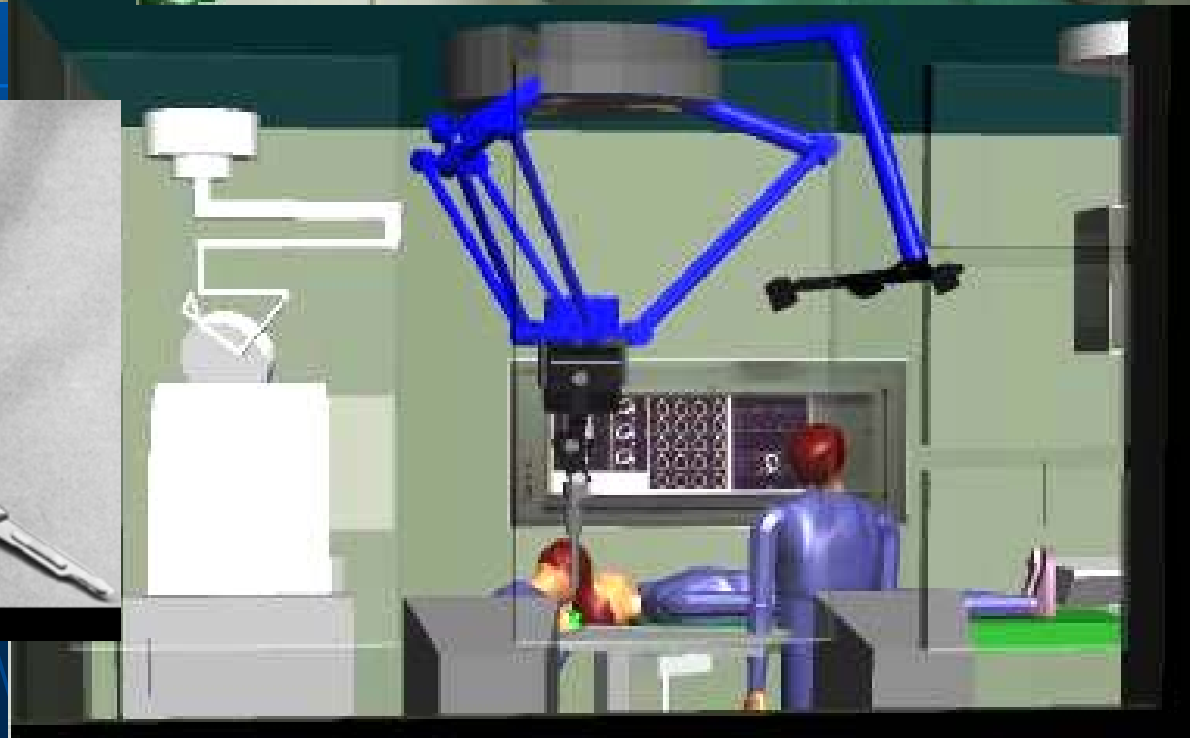


Image-Guided Minimally Invasive Surgery – Open System Concept


TOMOSCAN

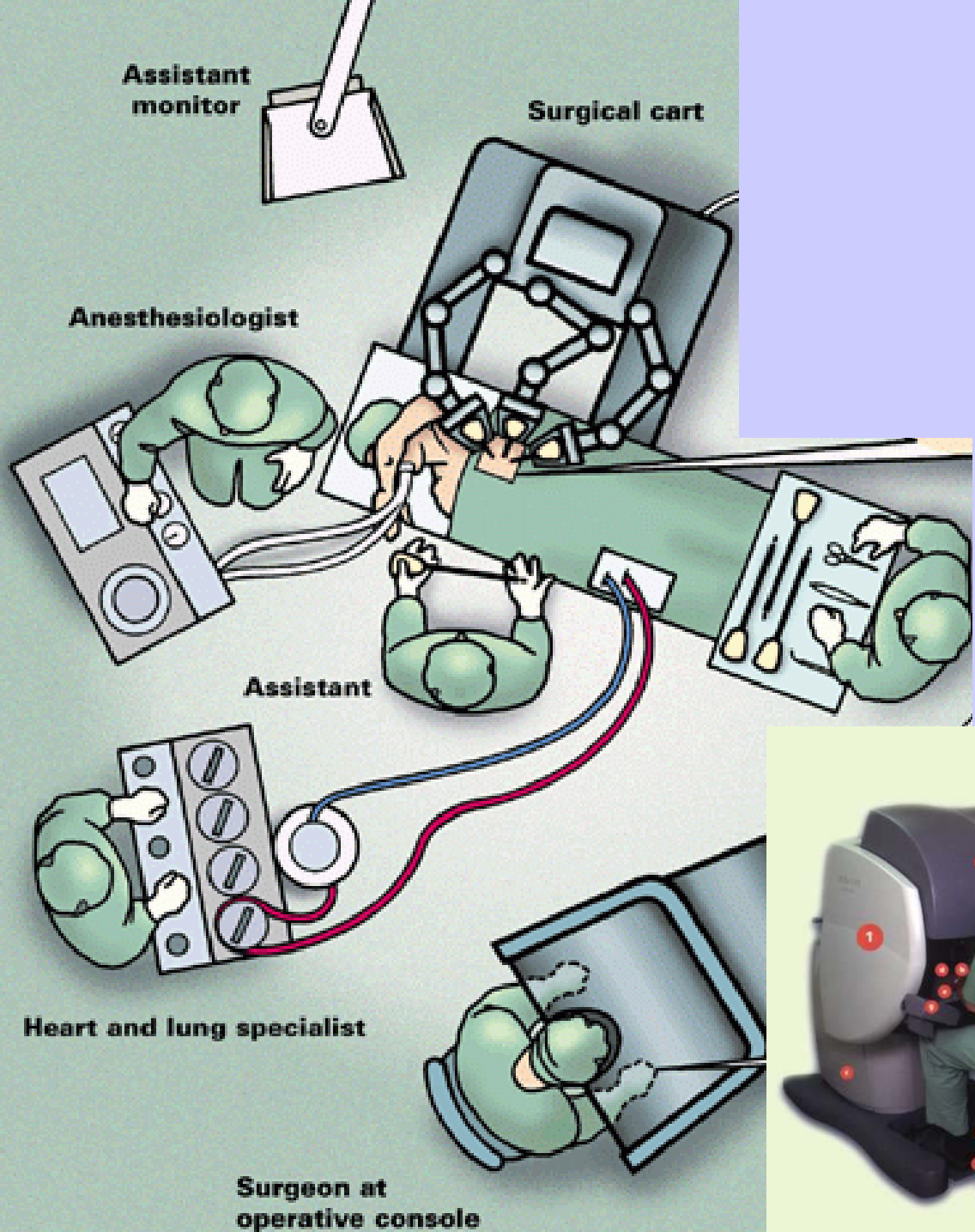


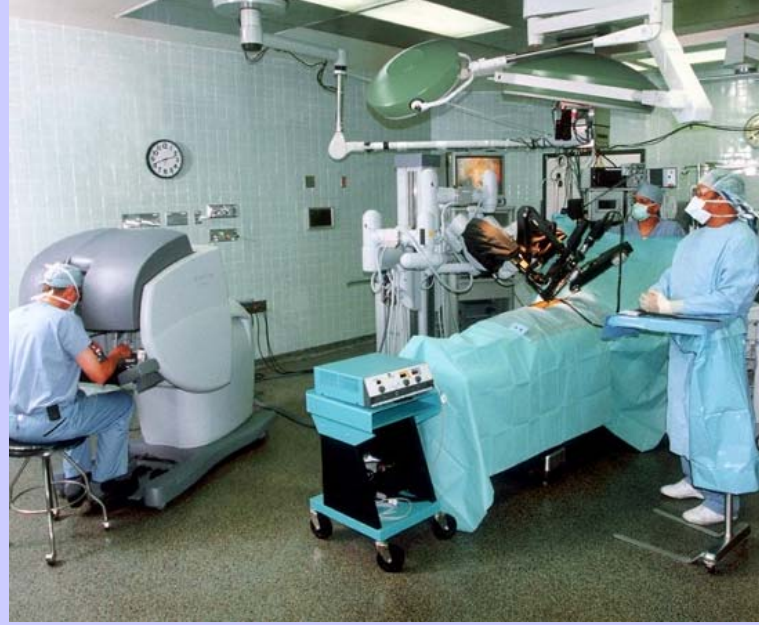


Forschungszentrum Karlsruhe - KISMET Project

Herzentrum Lepizig

ersity of Iowa


Assistant monitor
Surgical cart
Anesthesiologist
Assistant
Heart and lung specialist
Surgeon at operative console

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3
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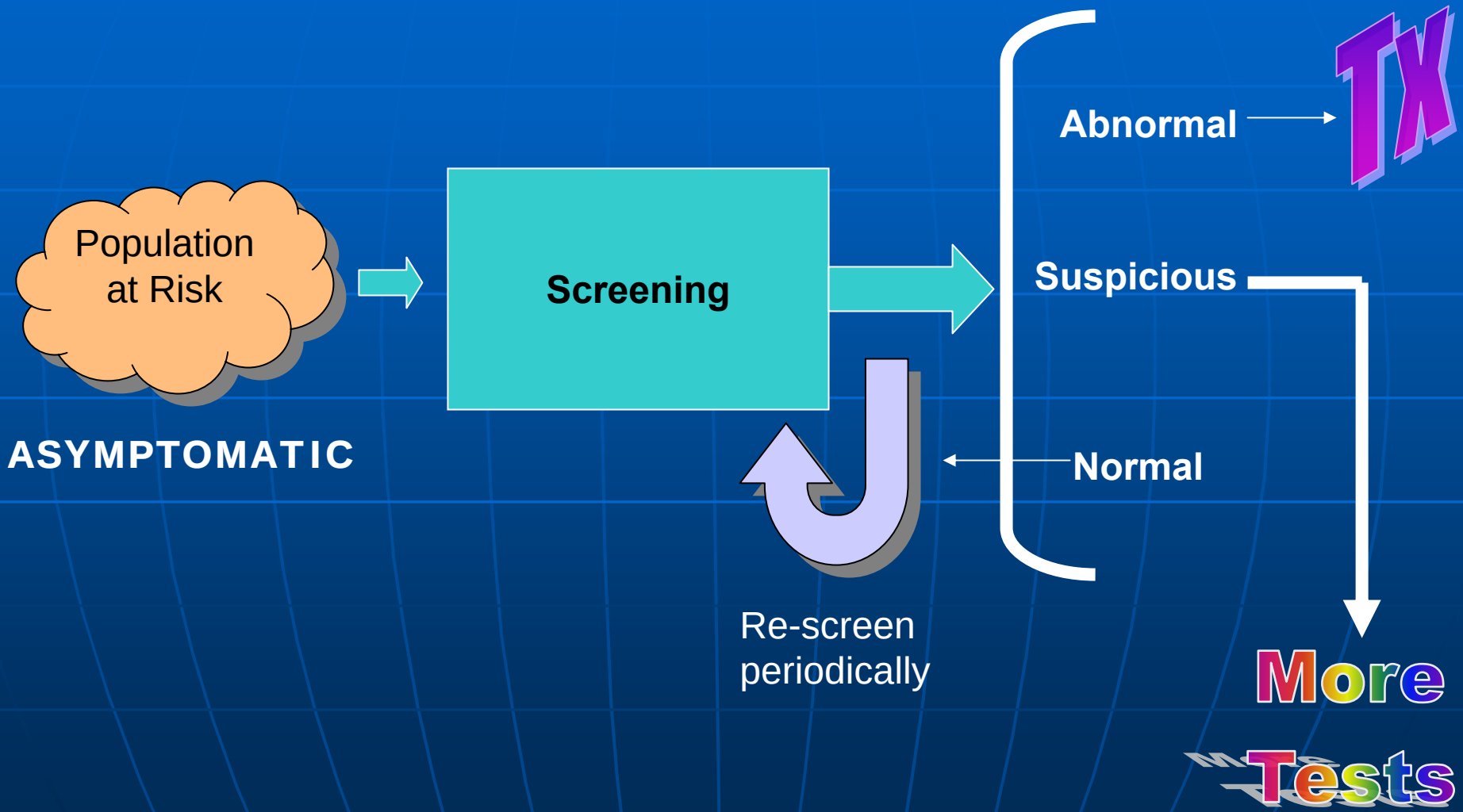
Image Guided Radiotherapy

- Clinical trials prove benefit for prostate IGRT
- Basic premise is that dose escalation will cure more often with fewer complications
- Problem: variation – in positioning,
  - Both accuracy and precision are important, but reproducibility is essential

Evidence of IGI Benefit?

- Image-guided radiotherapy of prostate
  - RTOG 3D CRT prostate with dose escalation
- Stereotactic breast biopsy
- Stents, especially coronary
- Others,...

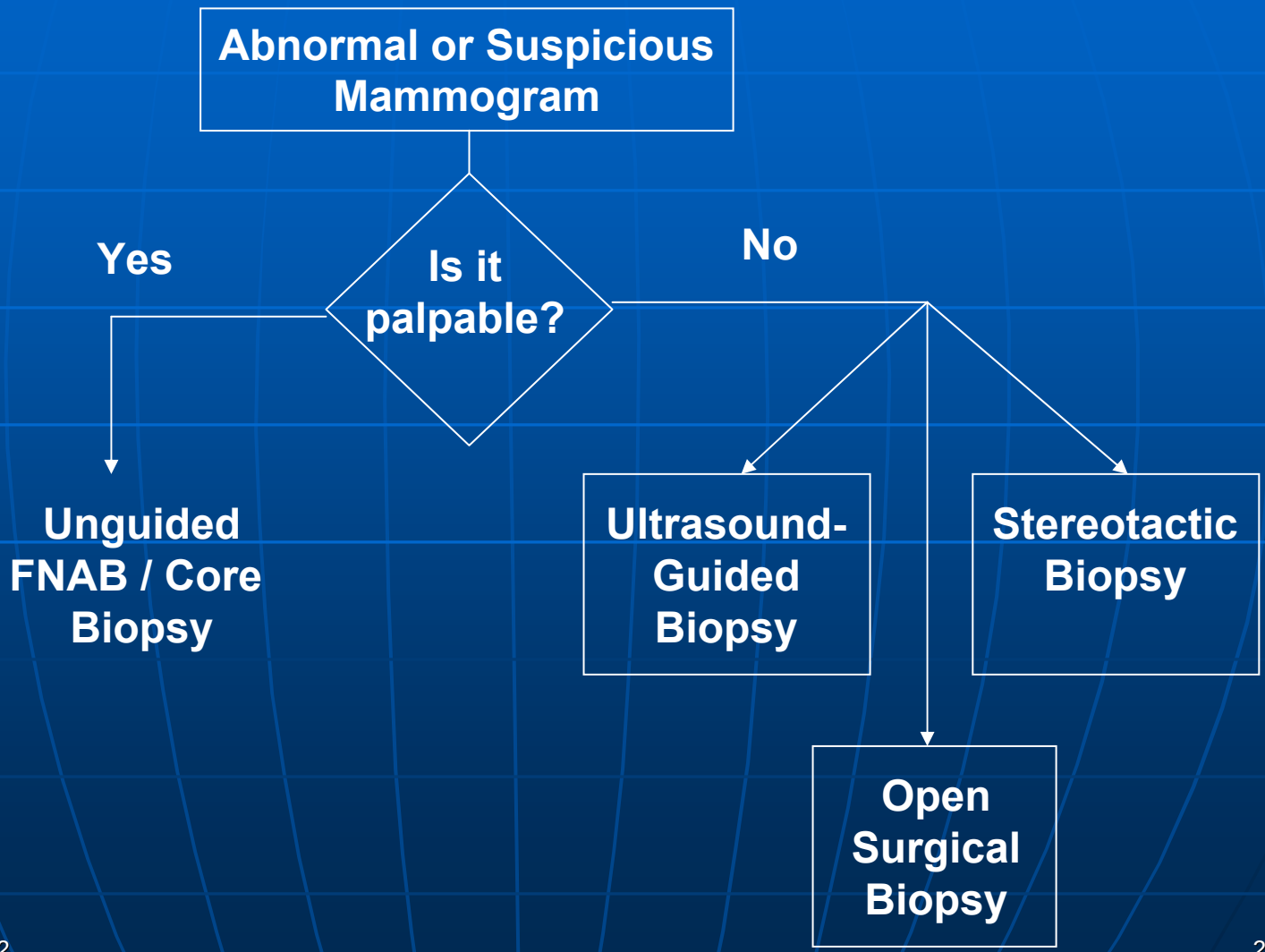
Screening Paradigm



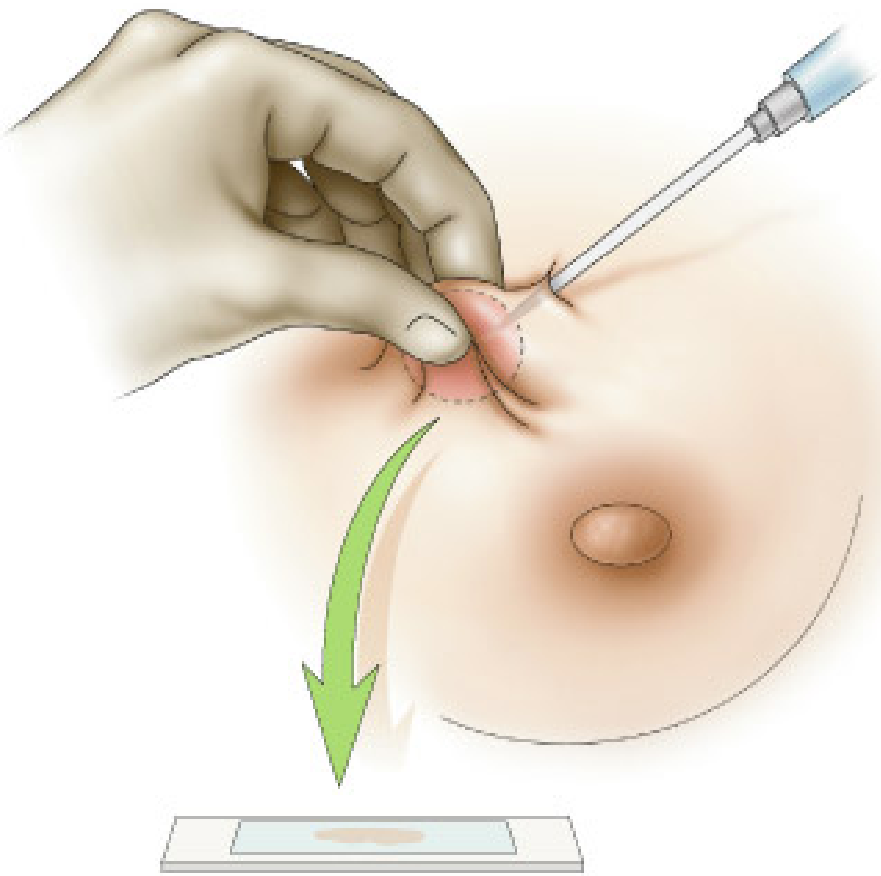
Principle

- Screening will identify those at highest risk; and diagnostic test to separate individuals who require treatment from those who don't.
  - Accuracy of diagnostic test/ procedure must be higher than screening test
  - Gold standard is pathologic diagnosis (based on tissue sampling)

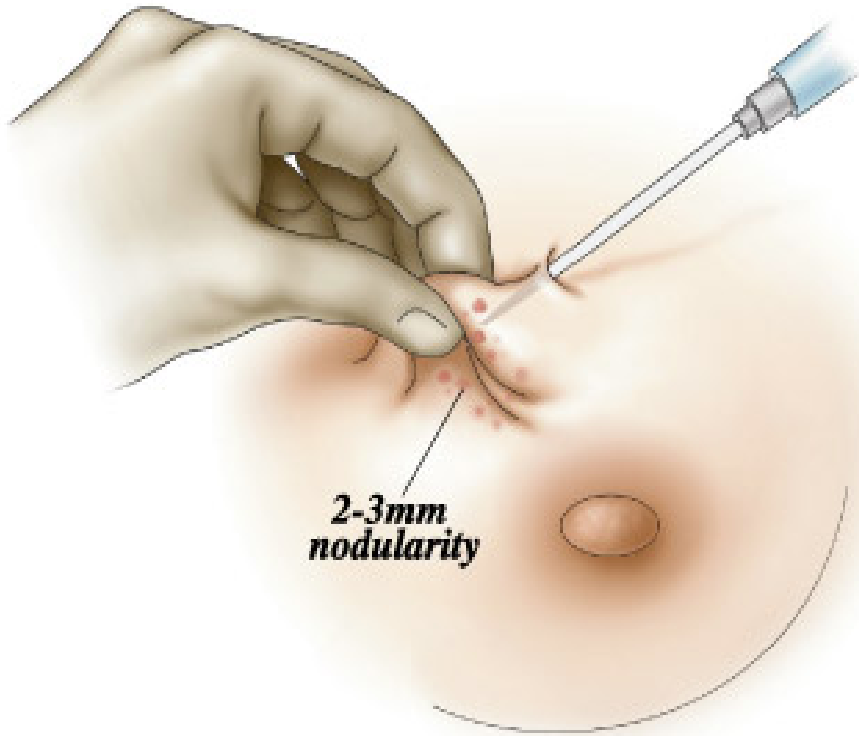
Breast Biopsy



CORE BIOPSY



A needle is placed within the dominant mass, the contents withdrawn, and examined under a microscope

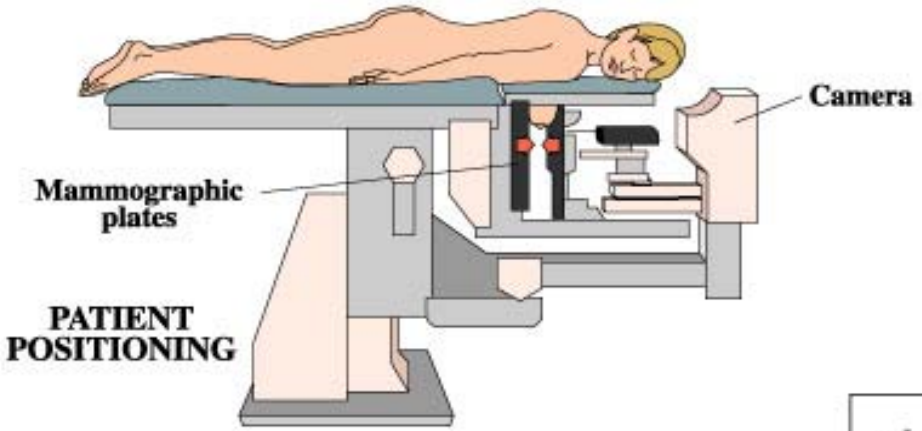


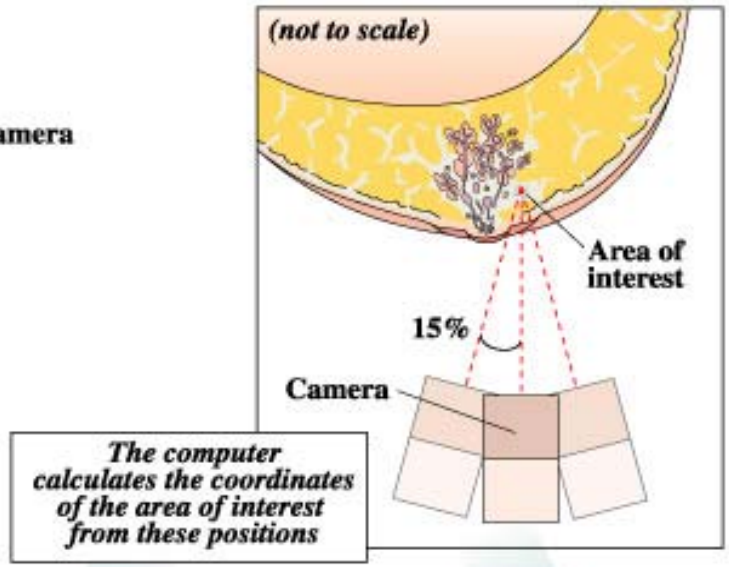
The nodularities are too small and diffuse to sample with the needle

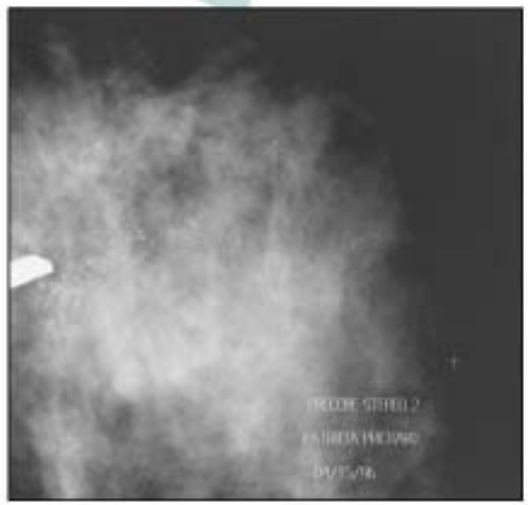
Vacuum assisted mammotomy

Ultrasound-guided breast biopsy

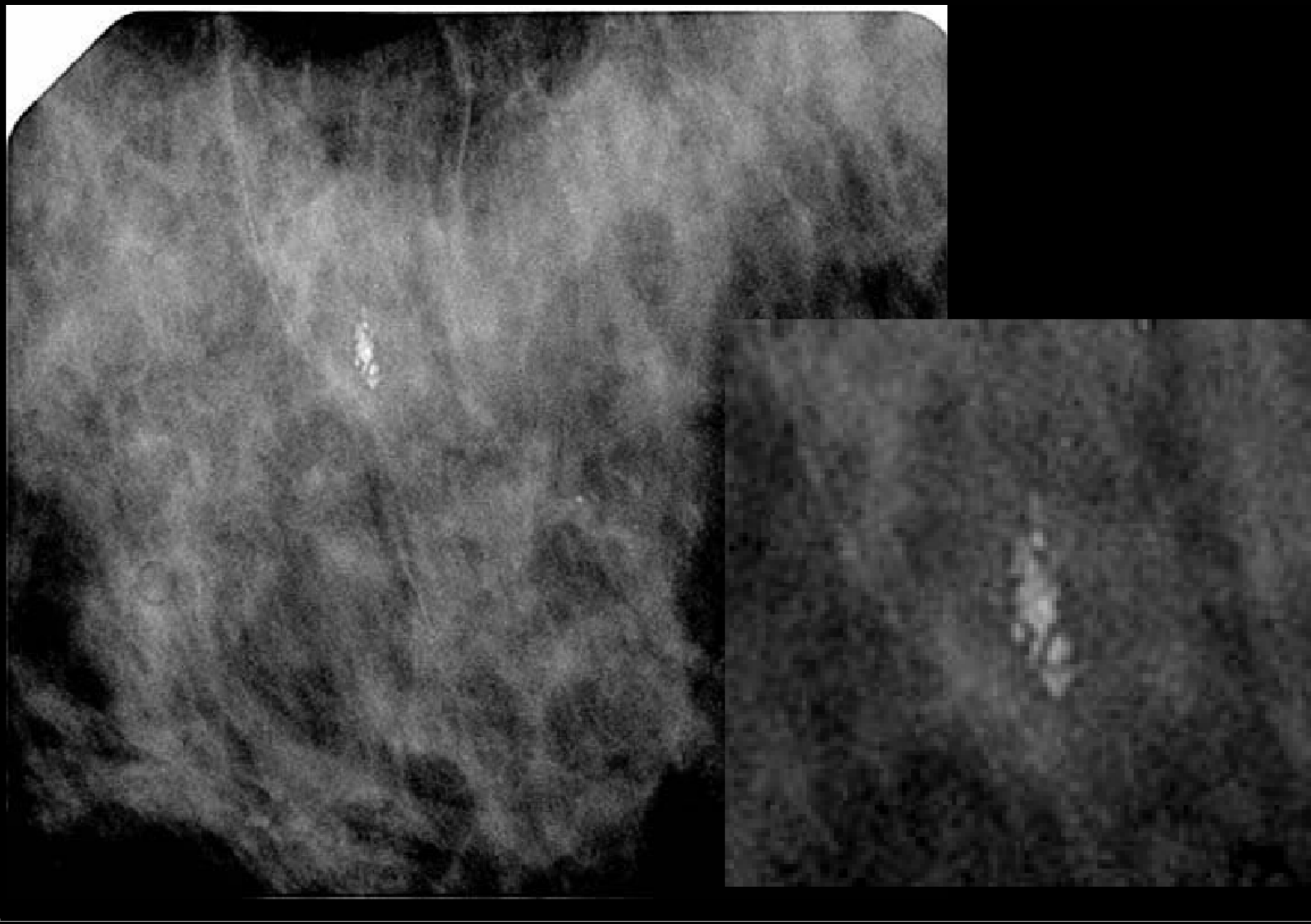
STEREOTACTIC BIOPSY

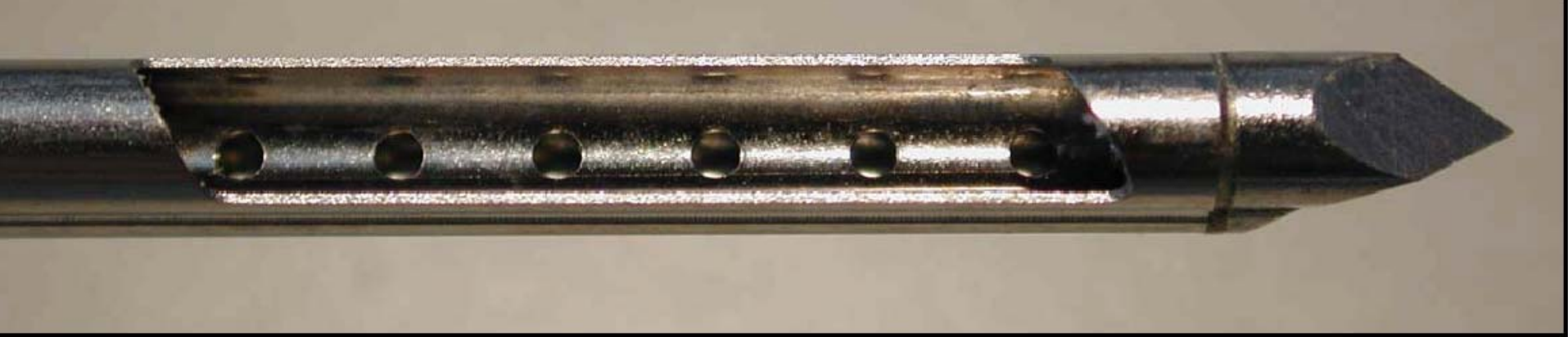


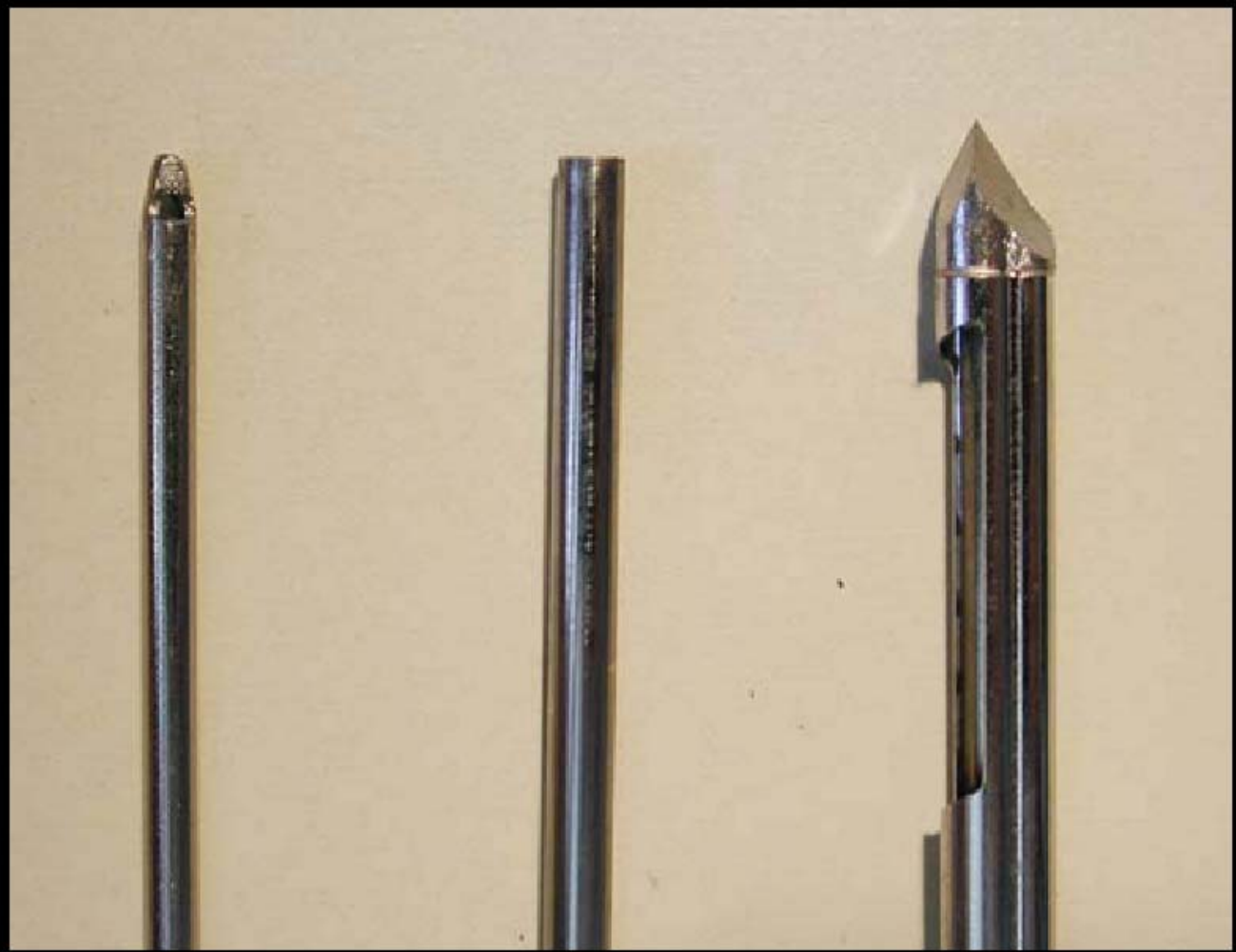


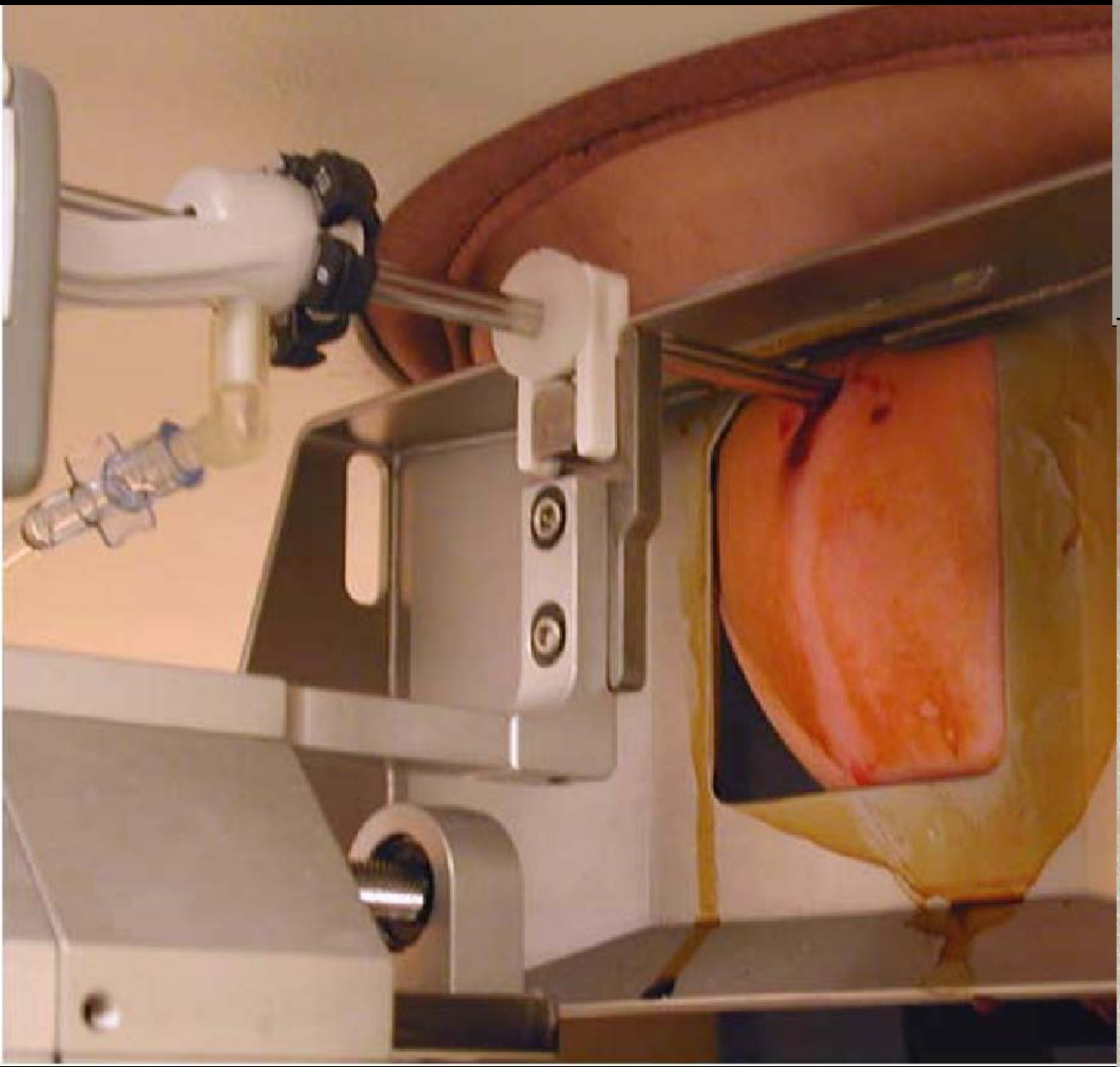


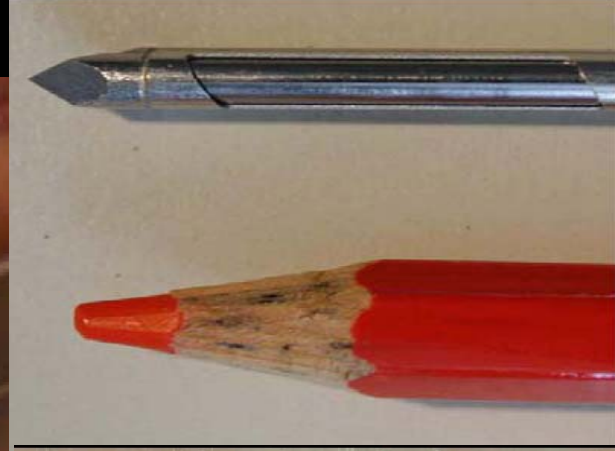

TREX











It's all about Options

- There is no single "best" solution
- Individuals want different therapy options
- Choices depend on the confidence, skill and demeanor of the surgeon / radiologist and their working relationship
- In different settings, the same patient will be offered different alternatives

Following up incidental findings may do more harm than good

- "A healthy 40-year-old", doctors sometimes joke, "is one who hasn't been worked up yet."
- Overdiagnosis
- Incidental findings = Incidentalomas
  - Benign lesions such as small liver cysts and granulomas that do not cause symptoms, or lead to morbidity or mortality.
  - Benign neoplasms, such as adrenal adenomas.
  - Anatomic abnormalities such as retroaortic renal veins.
  - Findings that show normal and age-appropriate degenerative changes, such as aortic atherosclerosis or spinal degeneration.
  - Findings related to old trauma or prior surgery.

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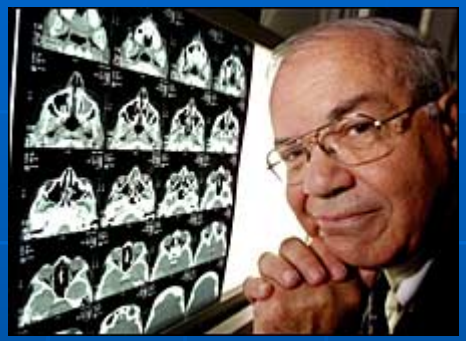
University of Alabama

[Taken from AuntMinnie.com, Eric Barnes, 9/5/02]

Bill Casarella, MD

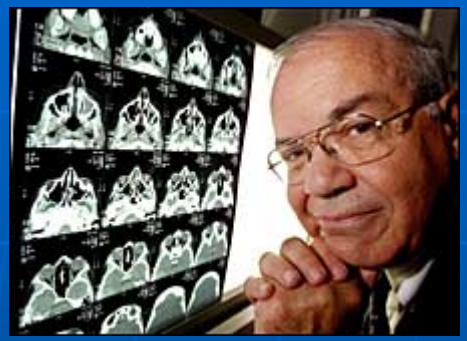


A doctor's story:
Scans may not be worth it

Last December, Dr. William Casarella, 64, the head of radiology at Emory Healthcare, had a virtual colonoscopy, a new screening test for colon cancer. The test uses a CT scanner to check for polyps in the colon, but it also images other organs. Casarella's test found several abnormalities, which led to painful and expensive follow-up tests.

"The virtual colonoscopy was relatively easy, and it didn't show any problems with my colon. But it found a small mass in my left kidney, a mass in my liver and seven or eight spots in my lung."

Bill Casarella, MD



"I was in the hospital for four days, with a chest tube, a bladder catheter, an epidural for pain control and a central IV for antibiotics. The incision went right through the chest wall, and it was extremely painful. It was hard to breathe and cough. It still feels numb. I was off work for 2 1/2 weeks, and it took four to six weeks before I felt normal. The bill for the surgery and the hospital stay was $47,000.

[The Atlanta Journal-Constitution: 7/16/02]

NIH
Consensus Development
Program

NIH STATE-OF-THE-SCIENCE CONFERENCE STATEMENT

Management of the Clinically Inapparent Adrenal Mass (Incidentaloma)

Final Statement
July 16, 2002

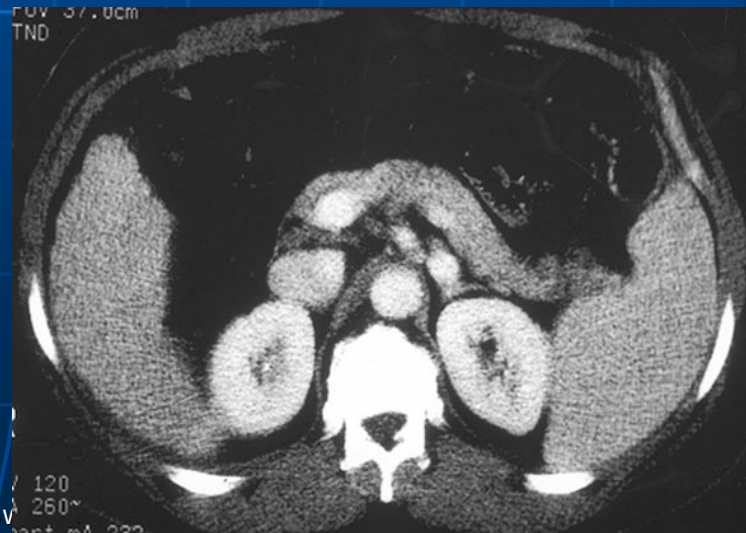
State-of-the-Science Statements

(formerly known as "Technology Assessment Statements")

NIH Consensus Development Program

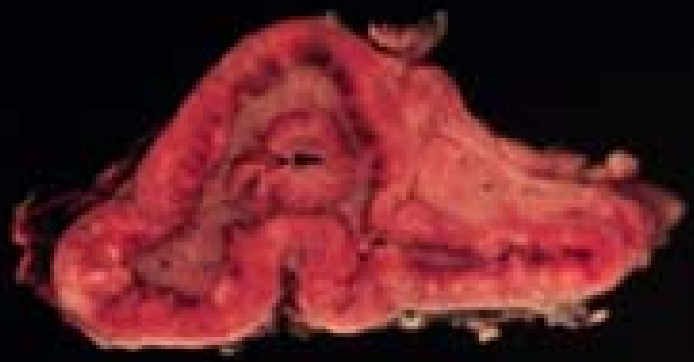
Incidental adrenal mass

- Common with contrast-enhanced CT
  - approximately 2% of contrast-enhanced CT examinations
- The majority of these are usually benign, even in oncologic patients with lung cancer.
- Incidental adrenal masses are a leading cause of radiology self-referral from abdominal CT examinations

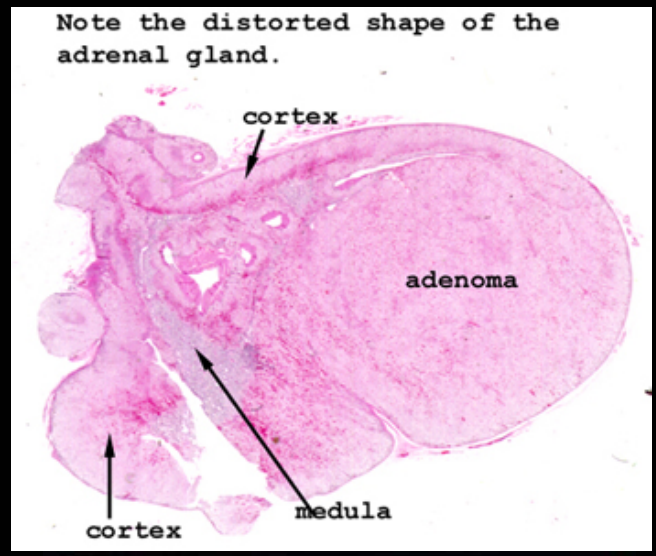


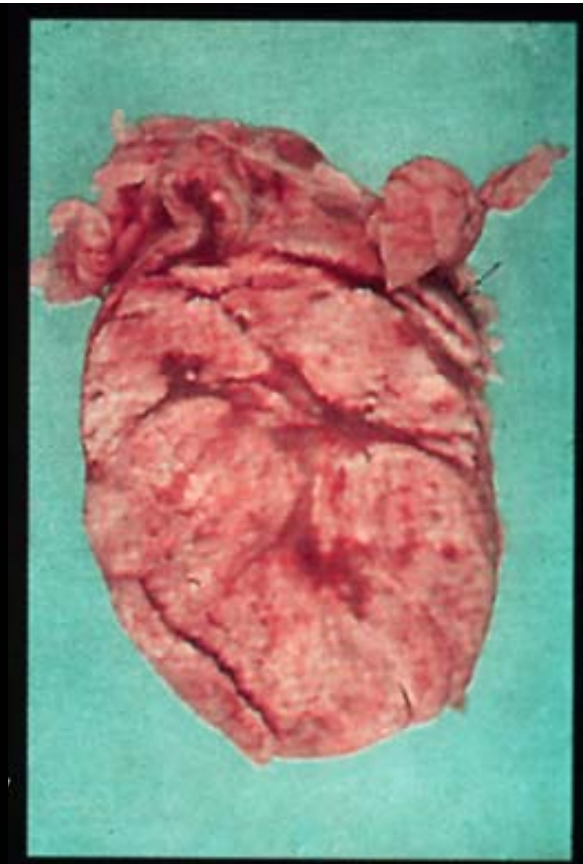
Adrenal Incidentaloma

Normal



Benign Adenoma





Conclusions

- The management of clinically inapparent adrenal masses is complicated by limited studies of incidence, prevalence, and natural history, including the psychologic impact on the patient who is informed of the diagnosis.
- ...the prevalence of clinically inapparent adrenal masses will continue to escalate.
- The low prevalence of adrenal cortical carcinomas and the relatively low incidence of progression to hyperfunction call into question the advisability of the current practice of intense, long-term clinical followup of this common condition.

- All patients with an incidentaloma should have a 1-mg dexamethasone suppression test and a measurement of plasma-free metanephrines.

Need for controlled studies

- The literature on adrenal incidentaloma has proliferated in the last several years.
- Unfortunately, the lack of controlled studies makes formulating diagnostic and treatment strategies difficult.
- The paucity of evidence-based data highlights the need for well-designed prospective studies.

Surgical options

- **Either open or laparoscopic** adrenalectomy is an acceptable procedure for resection of an adrenal mass. The choice of procedure will depend upon the likelihood of an invasive adrenal cortical carcinoma, technical issues, and the experience of the surgical team.

IGI Clinical Trials

- Most are single institution, one-armed, small n, early phase feasibility and safety

SPECIAL COMMUNICATION

JAMA, July 17, 2002—Vol 288, No. 3, 358-362.

The Continuing Unethical Conduct of Underpowered Clinical Trials

Scott D. Halpern, MSCE
Jason H. T. Karlawish, MD
Jesse A. Berlin, ScD

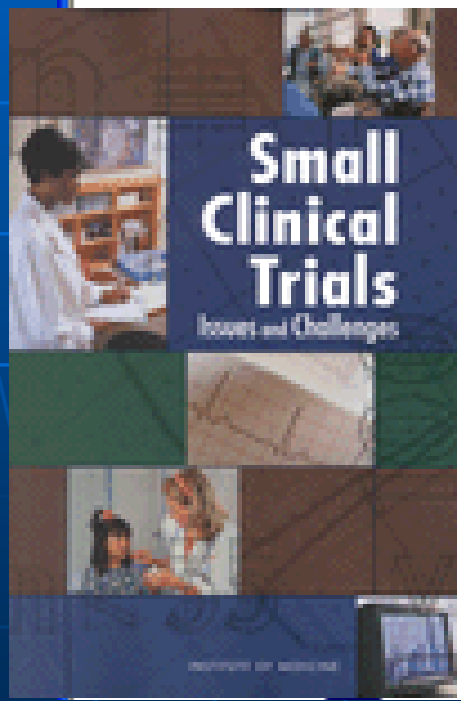
Despite long-standing critiques of the conduct of underpowered clinical trials, the practice not only remains widespread, but also has garnered increasing support. Patients and healthy volunteers continue to participate in research that may be of limited clinical value, and authors recently have offered 2 related arguments to support the validity and value of underpowered clinical trials: that meta-analysis may "save" small studies by providing a means

MORE THAN 20 YEARS HAVE passed since investigators first described the ethical
ducting randomized
(RCTs) with insuff
power.[1,2] Because suc
adequately test the u
eses, they have been
entifically useless"[2]
ethical in their exposure of participants to the risks and burdens of human re-

potential participants in underpowered trials so they may make autonomous enrollment decisions, and the circumstances in which the prospects

Despite long-standing critiques of the conduct of underpowered clinical trials, the practice not only remains widespread, but also has garnered increasing support….

Institute of Medicine Report on Small Clinical Trials (2001)



Small Clinical Trials: Issues and Challenges

Committee on Strategies for Small-Number-Participant Clinical Research Trials, Board on Health Sciences Policy

222 pages, 6 x 9, 2001.

ACRIN trials of IGI

- www.acrin.org = NCI Cooperative Group
- **Phase I/II Study of Percutaneous Radiofrequency Ablation of Bone Metastases Using CT Guidance (ACRIN Protocol A6661 - Open)**
- **Percutaneous Radiofrequency Thermal Ablation of Hepatocellular Carcinoma: A Multi-Center Phase II Trial to Determine the Success Rate of Local Tumor Eradication (ACRIN Protocol A6663 - In Development)**
- **Randomized Phase I/III Study of Systemic Chemotherapy With or Without Hepatic Chemoembolization for Liver-Dominant Metastatic Adenocarcinoma of the Colon and Rectum (ACRIN Protocol A6655 - Open)**

Summary of Requirements

- Post-screening: Reduce biopsy FN & TN (where FP is unlikely since histopathology is “gold standard”)
- Integrate screening / diagnosis in same system = “real time”
- More options to current procedures with MIS approach
- Incorporate eClinical Trial tools in systems as a design requirement

Conclusion

- IGI provides needed options to current modes of therapy
- Post-screening diagnosis and therapy are important potential areas for IGI
- Incidental findings produce dilemma – need immediate characterization
- Evidence for IGI benefit requires better methodology for in vivo testing of emerging technologies on humans